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Ezio Bombardelli

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YOUNG & THOMPSON  
209 Madison Street  
Suite 500  
ALEXANDRIA, VA 22314

EXAMINER

MCCORMICK, MELENIE LEE

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,980	<b>Applicant(s)</b> BOMBARDELLI, EZIO	
	<b>Examiner</b> MELENIE MCCORMICK	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 2,5 and 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants remarks with claim amendments submitted 06 October 2008 have been received and considered. Applicants' supplemental response and declaration submitted 21 October 2008 have also been received and considered.

Claims 1-9 are pending.

Claims 2, 5, and 7-8 stand withdrawn.

Newly amended claim 9 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 9, as amended, is drawn to a method for treating sexual dysfunction. As previously presented, the claim was ambiguous and could have been drawn to a composition having an intended use of treating sexual dysfunction. As stated in the previous Office Action, because it was not clear if a method was being claimed in claim 9, claim 9 was considered a composition for prior art purposes.

Newly amended claim 9 lacks unity with the originally examined composition claims because the originally examined composition claims and newly amended claim 9 because the special technical feature (the composition of claim 1) is not novel (as discussed in the prior art rejections of the previous Office Action). Therefore, the claims lack unity of invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

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prosecution on the merits. Accordingly, claim 9 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 3,-4 and 6 are presented for examination on the merits.

### ***Declaration***

The Declaration under 37 CFR 1.132 filed 21 October 2008 is insufficient to overcome the rejection of claims 1, 4 and 6 based upon Bombardelli et al. (EP 0693278) and Nishizawa et al. (JP 09157136), and claims 1, 3-4 and 6 over Di Perro (WO 02/098436), Dweek (1999) and Bombardelli (US 5,376,371), as set forth in the last Office action because: The declaration submitted by Applicant relies upon the disclosure of an unexpected result to overcome the obviousness rejections. Applicant's invention is therefore predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g. synergism) is therefore *ipsto facto* unpatentable. The gel formulations presented on pages 3-4 of the declaration contain either ; placebo, 1% esculocide, 2% ethyl ximenynate, 0.2%-80% purified extract of coleus, or the ingredients of example 1 on page 6 of the specification. The composition of example 1 appears to have a greater effect on flow in the vulvar mucosa after 60 minutes than the other formulations (groups 1-4) which were tested.

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This effect, however, may not necessarily be the result of the combination of esculoside, ethyl ximenyate, and extract of coleus because the composition of example 1 contains many more ingredients besides esculoside, ethyl ximenyate, and extract of coleus and it is not clear from the declaration that all of these ingredients were also present in the formulations tested. In addition, as previously stated, the unexpected result would be due to the combination of particular amounts of the components of the composition of example 1. These particular amounts are not reflected in the claims. Thus, the claims are not drawn to synergistic amounts of the components claimed and the declaration is not sufficient to overcome the obviousness rejection of the instant claims.

### ***Withdrawn Rejections***

The previous claim objections have been withdrawn in light of the amendments to claims 1 and 6 which corrected minor informalities.

The previous rejection under 35 U.S.C. 101 has been withdrawn in light of the amendment to claim 9, which is no longer drawn to an improper claim.

The previous rejection under 35 U.S.C. 112, second paragraph has been withdrawn in light of the amendments to claims 1 and 4, which now have antecedent basis and are no longer indefinite. In addition, the amendment to claim 6 overcomes the previous indefiniteness because it is now clear that the claim is drawn to a composition containing esculoside, *Coleus forskolii* purified extract, and ximenyic acid.

***Maintained Rejections***

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al. (EP 0693278) and Nishizawa et al. (JP 09157136) for the reasons set forth in the previous Office Action, which are restated below.

Bombardelli et al. beneficially teach that esculoside and esters of ximenyic acid are useful in the treatment of hair loss and in the stimulation of hair re-growth (see e.g. page 2, lines 33-35). Bombardelli et al. further teach that visnadin is also effective for this purpose (see e.g. page 2, lines 3-8) and that esculoside can replace visnadin (see e.g. page 2, lines 29-32). Bombardelli et al. also teaches that the ester of ximenyic acid is the ethyl ester (see e.g. page 2, line 7).

Bombardelli et al. do not explicitly teach that that forskolin or an extract containing forskolin is also used in treating hair loss or stimulating hair re-growth.

Nishizawa et al. beneficially teach that forskolin or an extract of a root of *Coleus forskolin* are used in a hair breeding agent (see e.g. English translation [0002]).

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Nishizawa et al. further teaches that the hair breeding agent has hair growth promoting activity (see e.g. [0001]).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the esculoside and ethyl ester of ximenyic acid taught by Bombardelli et al. with the forskolin or extract of a root of *Coleus forskolin* taught by Nishizawa et al. in order to prepare a composition comprising esculoside, ethyl ester of ximenyic acid and forskolin or extract of a root of *Coleus forskolin*, as instantly claimed because each were used in the prior art to promote hair re-growth. “The idea for combining them flows logically from their having been used individually in the prior art”; *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, See *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). It would have also have been obvious to use visnadin instead of esculoside because Bombardelli et al. teaches that they can be exchanged for each other.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference

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composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 3-4, and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Di Pierro (WO 02/098436 A) and Dweek (1999) in view of Bombardelli (US 5,376,371) for the reasons set forth in the previous Office Action, which are discussed below.

Di Pierro beneficially teaches a pharmaceutical and/or cosmetic composition containing escin, Ginkgo biloba dimeric flavones, ethyl ximentiate, and standardized Coleus forskolii extract (see e.g. page 2). Di Pierro further teaches that escin is derived from horse-chestnut seeds and has anti-edematous properties, probably due to a modification of the capillary permeability (see e.g. page 3, lines 3-5). Di Pierro also teaches that ethyl ximentiate is the ethyl ester of ximenininc acid (see e.g. page 4, lines 305) and that the standardized Coleus forskolii extracts contains forskolin therein (see



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e.g. page 4, lines 8-10). Di Pierro teaches that this composition is intended to be used to treat localized adiposities and cellulite (see .g. page 1, lines 1-2).

Di Pierro does not explicitly teach that the composition contains esculoside. Di Pierro also does not explicitly teach that the dimeric flavones of *Ginkgo biloba* comprise amentoflavone.

Dweek beneficially teaches that esculoside is derived from horse chestnut tree and that increases capillary resistance and reduces oedema (see e.g. page 2).

Bombardelli beneficially teaches that amentoflavone is useful in compositions for reducing fat deposits (see e.g. col 4, example 4 and claim 3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the esculoside taught by Dweek for the escin taught by Di Perro in the composition comprising *Ginkgo biloba* dimeric flavones, ethyl ximentiate and extract containing forskolin. A person of ordinary skill in the art would have had a reasonable expectation of success in doing so based upon the teaching of Dweek that esculoside increases capillary resistance and reduces oedema, which is the same function taught by Di Pierro of escin. A person of ordinary skill in the art would have also had a reasonable expectation of success in using amentoflavone as the particular dimeric flavone from *Ginkgo biloba* based upon the disclosure Bombardelli that amentoflavone is useful in fat deposit reduction (see e.g. col 4, Example 4 and claim 3). This is especially true given that is essentially the same the intended use that Di Pierro teaches for the composition, which is treating localized adiposities and cellulite.

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With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant argues that the combined cited references do not disclose or suggest each and every element of the claims as amended and that the references teach away from the claimed subject matter. In addition, Applicant argues that the claimed invention achieves surprising and unexpected results indicative of non-obviousness.

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Applicant argues that the cited references teach away from the invention of claims 1-9 because the invention of claims 1-9 is directed toward a topical composition for the treatment of sexual dysfunction and that the references relate to composition to promote hair growth. This is not found persuasive, however, because as previously stated, the intended use of the instantly claimed composition does not provide a structural difference which distinguishes it over the prior art. Applicant argues that because the references teach treatment for hair loss, the skilled person faced with the problem of finding a new composition for treating sexual dysfunction would not look at the cited references which deal with completely different problems. This reasoning is not accepted because the intended use is not patentable and Bombardelli and Nishizawa render obvious the instantly claimed combination of ingredients present in the instantly claimed composition, regardless of the intended use of the composition. The disclosure of a different intended use than instantly claimed is not a teaching away from the combination of ingredients. A person of ordinary skill in the art would be motivated to combine the instantly claimed ingredients because of the disclosure of Bombardelli and Nishizawa that these ingredients are all useful for treating hair loss. The reason that Applicant would combine these ingredients need not be the same as the reason for combining which is suggested by the prior art. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

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Applicant has not specifically addressed the combination of ingredients rendered obvious over Di Perro and Dweek in view of Bombardelli, which have a different intended use from Bombardelli and Nishizawa. Nonetheless, the intended use instantly claimed does not distinguish the claims over the composition rendered obvious by Di Perro and Dweek in view of Bombardelli.

Applicant also argues that the active ingredients of the instantly claimed composition were unexpectedly found to behave synergistically. This reasoning is also not accepted, as discussed above, because synergism is highly dependent upon particular amount of ingredients. The instant claims do not recite any particular synergistically effective amounts. In addition, as discussed above (see Declaration), it is not clear that the formulations of groups 1-4 contained all of the additional ingredients which are present in the gel according to example 1 and in the same amounts as the gel of example 1. It is therefore not clear what effect, if any, these numerous additional ingredients had in the experiment presented on pages 9-10 of Applicant's remarks and in the Declaration.

The rejection is therefore deemed proper and is maintained.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELENIE MCCORMICK** whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655